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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,471	11/04/1998	STEFAN ROSE-JOHN	012627-009	2240

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EXAMINER

O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 01/24/2003

31

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/142,471

Applicant(s)

ROSE-JOHN, STEFAN

Examiner

Eileen B. O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-9,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-9,11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-5,7-9,11 and 12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims Status

2. Claims 1-5, 7-9, 11 and 12 are pending in the instant application.

Election/Restrictions

3. Applicant's election with traverse of Group I in Paper No. 29 is acknowledged. The traversal is on the ground(s) that a search of both groups of claims would not be burdensome, as a search of fusion polypeptide comprising a cytokine and cytokine receptor, DNA encoding, and a method of treating cells with the fusion polypeptide would result in methods of gene therapy using these polypeptides as well, and the Office has not set forth an explanation of how a search of the claimed invention would be burdensome. This is not found persuasive because consistent with current patent practice, a serious search burden may be established by (A) separate classification thereof: (B) a separate status in the art when they are classifiable together: (C) a different field of search:. These criteria were met in the above restriction. As stated in the MPEP § 803, "a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02." Additionally, although a search of the subject matter of Invention II may substantially overlap a search of the subject matter of invention I, the methods of treatment would require substantial separate consideration for enablement, and the search and consideration of both inventions would therefore be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Claim 5 is withdrawn as being drawn to a non-elected invention.

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Claims 1-4, 7-9 and 11 and 12 in so far as they encompass treatment of cells with fusion polypeptide are currently under examination.

Specification

4. The specification has been amended as requested by Applicants in Paper No. 29, filed Oct. 29, 2002.

Sequence Compliance

5. The application is now in compliance with 37 CFR 1.821.

Withdrawn Rejections

6.1 The rejection of claims under 112 § 1 is withdrawn in view of Applicants' amendment.

6.2 The rejections of claims under 112 § 2 is withdrawn in view of Applicants' amendment except for the rejections below.

Claim Objections

7.1 Claim 11 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

7.2 Claims 11 and 12 are also objected because of the following informalities: they recite non-elected inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-4, 7-9, 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8.1 Claims 7-9, 11 and 12 are indefinite because they depend upon cancelled claim 6.

8.2 Claims 1-4 are vague and indefinite because it is not clear in claim 1 if the polypeptides have mutual affinity for each other or to another polypeptide. Also, the recitation of the other polypeptide "being a cytokine" and also the recitation of "as ligand" is redundant and not clear.

It is suggested the claim be re-written as follows:

-- A conjugate comprising two polypeptides, one polypeptide being a cytokine receptor, or subunit thereof, and the other polypeptide being a cytokine, or subunit thereof, that binds to said cytokine receptor, wherein the polypeptides are linked to each other via a polypeptide linker. --

Applicant is reminded that if this type of language is adopted claim 2 would need to be amended to recite "cytokine" and not "ligand".

8.3 Claims 11 and 12 are indefinite because although claim 11 has been amended it is still indefinite, because it is not clear how incubating an expression plasmid with cells would influence the interaction between proteins.

8.4 Claims 11 and 12 are indefinite because although claim 11 has been amended it is still an indefinite method claim. It is not clear what proteins are being influenced, and also the method

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for influencing (as recited in the preamble) is different from the method of determining said interaction (as recited in the conclusion).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-4, 7-9, 11 remain rejected and new claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sui et al, PNAS, Vol. 92, March 1995, and further in view of Wong et al, WO 96/04314, Feb. 15, 1996, for reasons of record in the previous Office Actions, Paper No. 17 at pages 6-7, Paper No. 23 at pages 5-7, and Paper No. 26.

Applicant's arguments have been fully considered but are not deemed persuasive. Applicant argues on page 8 that Sui et al. only discloses the separate administration of IL6 and IL6-receptor, however Sui et al. teaches the administration of the IL-6/IL-6R **complex** (for example, see the sentence bridging the first and second columns on page 2860), and even if IL-6 and IL6-R were added separately, they would still form a complex before activating the cells. Applicant also argues on pages 8-9 that the purpose of Wong et al. is to provide a MCH-peptide complex in which the MCH molecule and the peptide are positioned such that they can activate T-cells, and is completely different from the presentation of a cytokine complexed with a cytokine receptor. This argument has been fully considered but is not deemed persuasive because this is not different, since the point of linking IL-6 and IL-6R is to also position them to activate the cells more effectively. Applicant also argues on page 9 that they surprisingly found that the effects of a conjugate of IL-6 and IL-6R are increased dramatically over the effects of the two polypeptides separately, however, Sui et al also found that a complex of IL-6 and IL-6R

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had increased activity over the individual polypeptides (see Table 1, first three lines of the Table). Therefore, the rejection is maintained.

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312.

The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

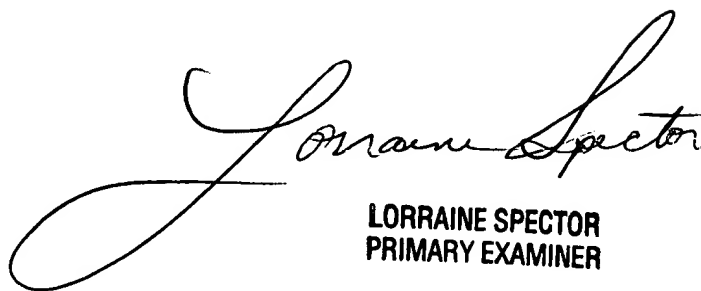
Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



**LORRAINE SPECTOR
PRIMARY EXAMINER**